

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/242,772	VAN DE VEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Young J. Kim	1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the After Final Amendment received on February 16, 2006.
2. ☒ The allowed claim(s) is/are 53-55.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Gwen Wood on April 14, 2006.

The application has been amended as follows:

In the Claims:

54. (Currently Amended)      An isolated hybrid nucleic acid sequence consisting of a ~~nucleic acid fragment fused to exons 3 to 5 of PLAG1 of claim 53, wherein said fragment consists of 509 base pairs corresponding to exon 1 of CTNNB1, wherein said nucleic acid fragment is a CTNNB1 translocation partner of said PLAG1, and further wherein said isolated hybrid nucleic acid sequence allows the diagnosis of a cell containing said hybrid nucleic acid sequence as a tumor cell~~ 509 base pairs, said hybrid nucleic acid sequence consisting of a nucleic acid fragment fused to exons 3 to 5 of PLAG1 of claim 53, wherein said nucleic acid fragment is a CTNNB1 translocation partner of PLAG1, further wherein said nucleic acid fragment is from exon 1 of CTNNB1, wherein said hybrid nucleic acid is produced by amplification with a pair of primers consisting of SEQ ID NO: 103 and SEQ ID NO: 104 from a pleomorphic adenoma sample.

55. (Currently Amended)      An isolated hybrid nucleic acid sequence consisting of a ~~nucleic acid fragment fused to exons 2 to 5 of PLAG1 of claim 53, wherein said fragment consists of 614 base pairs corresponding to exon 1 of CTNNB1, wherein said nucleic acid fragment is a~~

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~~CTNNB1 translocation partner of said PLAG1, and further wherein said isolated hybrid nucleic acid sequence allows the diagnosis of a cell containing said hybrid nucleic acid sequence as a tumor cell~~  
614 base pairs, said hybrid nucleic acid sequence consisting of a nucleic acid fragment fused to exons 2 to 5 of PLAG1 of claim 53, wherein said nucleic acid fragment is a CTNNB1 translocation partner of PLAG1, further wherein said nucleic acid fragment is from exon 1 of CTNNB1, wherein said hybrid nucleic acid is produced by amplification with a pair of primers consisting of SEQ ID NO: 103 and SEQ ID NO: 104 from a pleomorphic adenoma sample.

#### *Examiner's Comment*

The support for the limitations of the Examiner's Amendment can be found in the following sections:

The support for isolated hybrid nucleic acid consisting of 509 bp and 614 bp is found on page 43, line 37 through page 44, line 10. The primers identified as, "NECAT-UP" and "MV6" are identified as being SEQ ID NO: 103 and 104, respectively, on page 38, lines 34-38 of the instant specification and evidenced on page 29 of the paper copy of the sequence listing.

The support for the structural limitation of the isolated hybrid nucleic acid consisting of 509 bp and 614 bp are supported by the disclosure found on page 44, lines 3-10.

The typographical error in the phrase, "The PCR product of 605 bp contains an extra 105 bp..." appearing on page 44, lines 5-6 (typographical error underlined) is corrected in the amendment received on October 3, 2005 in response to the Office Action mailed on June 29, 2005. The amendment does not introduce new matter as the error is solely due to typographical error as explicitly discussed on pages 4-5 of the Office Action mailed on June 29, 2005.

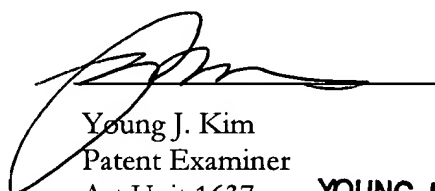
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*Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Patent Examiner  
Art Unit 1637

3/15/2006

**YOUNG J. KIM  
PATENT EXAMINER**

yjk